NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MYLAN INC. and MYLAN PHARMACEUTICALS INC., Plaintiffs, v. SMITHKLINE BEECHAM CORPORATION (n/k/a GLAXOSMITHKLINE LLC) d/b/a GLAXOSMITHKLINE, SMITHKLINE BEECHAM P.L.C. (n/k/a SMITHKLINE BEECHAM, LIMITED), SMITHKLINE BEECHAM (CORK) LIMITED (successor to SB PHARMCO PUERTO RICO, INC.), APOTEX INC., and APOTEX CORPORATION Defendants.	Civil Action No. 10-4809 (JAP) **MEMORANDUM OPINION**

PISANO, Judge

This matter comes before the Court upon three motions. The first is a Motion for Summary Judgment by Defendants GlaxoSmithKline LLC (formerly known as SmithKline Beecham Corporation), SmithKline Beecham, Limited (formerly known as SmithKline Beecham, P.L.C.), and SmithKline Beecham (Cork) Limited (collectively "GSK"). (DE 183.) The second motion is a Motion for Summary Judgment by Defendants Apotex Inc. and Apotex Corporation (collectively "Apotex"). (DE 178.) The third motion is a Motion to Strike the Expert Report of Mark Gleason filed by Defendants GSK. (DE 187.) Plaintiffs Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan" or "Plaintiffs") oppose all three motions. The Court has considered the parties' submissions and decided the matter without oral argument

pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, the Court will grant GSK's Motion for Summary Judgment, will grant Apotex's Motion for Summary Judgment, and will deny GSK's Motion to Strike the Expert Report of Mark Gleason as moot.

I. BACKGROUND

In June 2007, GSK sued Mylan for infringing U.S. Patent No. 7,229,640 ("the '640 patent"), which relates to the antidepressant drug Paxil CR. (GSK's Statement of Undisputed Material Facts ¶ 1, DE 184-1.) To settle the '640 patent litigation, GSK and Mylan entered into a Patent License and Settlement Agreement (the "License Agreement") on August 10, 2007. (*Id.* ¶ 2.) The original License Agreement granted Mylan an exclusive license (even as to GSK) under the '640 patent to sell generic Paxil CR[1] for the remaining life of the '640 patent, almost nine years. (*Id.* ¶¶ 3, 4.)

Pursuant to Section VII of the License Agreement and as required by federal law, GSK and Mylan submitted the License Agreement to the Federal Trade Commission ("FTC"). (*Id.* ¶ 6.) The License Agreement called for a thirty day "FTC Review Period" so that the FTC could review the agreement's terms and present any objections. (*See* License Agreement, Section VII(b)-(c), Ex. 10 to Adamson Decl., DE 204-3.) In September of 2007, the parties held several meetings with FTC representatives. (GSK's Statement of Undisputed Material Facts ¶¶ 8-10, 14.)

[1] Paxil CR's generic form is "paroxetine hydrochloride controlled release" or "paroxetine HCl controlled release." A generic product is approved under an abbreviated new drug application ("ANDA"). Alternatively, an "authorized generic" product is approved under a new drug application ("NDA") but is sold at lower price than its branded equivalent. (*See* Mylan Br. at 4 n.2, DE 208; Apotex Br. at 5, DE 180.)

According to Kevin Grady, an attorney representing Mylan, (*id.* ¶ 9), the FTC raised two concerns with the original License Agreement. (Grady Tr. 34:9-16, Ex. 14 to Anderson Decl., DE 204-5.) The first concern was the delayed launch of Mylan's generic Paxil CR. (*Id.*) The second concern was the duration of the exclusive license granted to Mylan. (*Id.*) However, the FTC never launched a formal investigation of the License Agreement. (*See, e.g.*, GSK's Statement of Undisputed Material Facts ¶ 36.)

After meetings with the FTC, GSK and Mylan amended the License Agreement. The second of those amendments (the "Second Amendment") was executed on September 27, 2011. Section II of the License Agreement was amended to read, in relevant part:

> (c) GSK hereby grants Mylan a non-transferable, non-sublicensable, royalty-bearing license under the '640 patent, effective automatically as of the Authorization Date, so as to (i) allow Mylan to make, have made, sell, have sold, and import Mylan Generic Paroxetine Products in the Territory as of and after the Authorization Date, and (ii) sell and have sold Generic Equivalents in the Territory as of and after the Authorization Date . . . . The foregoing licenses shall be exclusive (even as to GSK) in favor of Mylan for all Generic Paroxetine Products, except as otherwise set forth in subsection (e) below.
>
> (e) Also, GSK or its Affiliate may commence marketing and selling generic paroxetine hydrochloride controlled or modified release products pursuant to its Paxil CR® NDA ("Authorized Generic Products") at the end of the second year after Mylan launches its Generic Paroxetine Products.

(License Agreement, Section II(c); Section II(e), Ex. 1 to Dubiansky Decl., DE 185-1.) Mylan launched its generic Paxil CR on May 14, 2008. (GSK's Statement of Undisputed Material Facts ¶ 38.) The parties made no further amendments to the License Agreement after September 27, 2011, and the underlying '640 patent litigation between GSK and Mylan was dismissed.

In 2010, GSK began settlement negotiations in a different lawsuit, this one against Apotex. (Apotex's Statement of Material Facts ¶ 1, DE 181.) Apotex initially wanted an all-

cash settlement, but GSK identified a future stream of income derived from certain GSK products, one of those being Paxil CR. (*Id.* ¶ 2.) Eventually, GSK and Apotex entered into a settlement agreement in May 2010. (Binding Agreement of Terms in Settlement of Litigation, Ex. O to Saveriano Cert. at 1, DE 179-15.) The terms provided for a $300 million cash payment to Apotex. (*Id.* at 2.) Additionally, Apotex was entitled to a guaranteed minimum of $180 million to be earned through sales of GSK products. (*Id.* at 2.) If Apotex failed to reach the minimum profit, GSK was required to remit "make-up payments" in order to reach the $180 million mark. (*Id.*) One of the GSK products that would contribute to the guaranteed minimum was Paxil CR, and the settlement terms required GSK and Apotex to enter into an "Exclusive Supply and Distribution Agreement" with regard to authorized generic Paxil products. (*Id.* at 4.) GSK was also required to indemnify Apotex from any claims related to the sale of authorized generic Paxil products. (*Id.* at 5.)

During settlement negotiations, Apotex knew of the existence of the GSK-Mylan License Agreement. (Apotex's Statement of Material Facts ¶ 8.) Apotex counsel requested a copy of the License Agreement, but GSK denied the request explaining that the License Agreement was confidential. (*Id.* ¶ 16.) Nonetheless, GSK advised Apotex that GSK's supply obligation to Mylan ended by June of 2010. (*Id.* ¶ 11.)

Mylan contends that Apotex never followed up with GSK in regard to the License Agreement, never pressed GSK to share a copy, and did not ask Mylan to waive the confidentiality provisions. (Mylan's Response to Apotex's Statement of Undisputed Material Facts ¶ 16; DE 206) Moreover, Mylan issued two press releases related to its License Agreement with GSK. (Apotex's Statement of Material Facts ¶10.) The first was issued in October of 2007 and stated that, under the License Agreement, "Mylan is provided patent

licenses and the right to market all three strengths of Paroxetine . . . beginning no later than October 1, 2008." (Adamson Decl., Ex. 35, DE 205-1.) In the second press release, issued on May 14, 2008, Mylan announced the launch of two dosage strengths of paroxetine hydrochloride, pursuant to its License Agreement, "which remains confidential," and it touted its 180 days of generic exclusivity. (Adamson Decl., Ex. 36, DE 205-2.)

On August 30, 2010, pursuant to their settlement agreement, GSK and Apotex signed a Supply and Distribution Agreement for authorized generic Paxil products. (Ex. K to Saveriano Cert., DE 179-1; Apotex's Statement of Material Facts ¶¶ 18, 19.) The "Exclusive Supply" section of the Supply and Distribution Agreement states:

> During the Supply Term and subject to the terms and conditions of this Agreement, [GSK] agrees to exclusively supply and sell to [Apotex], and [Apotex] agrees to exclusively purchase from [GSK] the [GSK] Supplied Products.
>
> [Apotex] hereby agrees and acknowledges that, subject to the terms and conditions of this Agreement, [Apotex] and its Affiliates shall received one hundred percent (100%) of its (and its Affiliates') requirements of [GSK] Supplied Product in the Territory from [GSK] or [GSK's] Affiliates commencing on the Effective Date.

(Ex. K to Saveriano Cert. at §3.1(a)(i)-(ii).) Apotex commenced sales of authorized generic Paxil CR in November 2010.

After learning that Apotex was attempting to take orders from generic paroxetine CR customers, Mylan filed the instant action on September 20, 2010. (DE 1.) Mylan asserts four causes of action: (1) breach of contract by GSK; (2) breach of the implied covenant of good faith and fair dealing by GSK; (3) inducement to breach contract by Apotex; and (4) tortious interference with a contract by Apotex. (Second Amended Complaint, DE 166.)

Mylan also sought a preliminary junction against GSK and Apotex seeking to prohibit GSK's manufacturing, distributing, and selling of authorized generic Paxil CR and seeking to prevent the launch of Apotex's authorized generic Paxil CR. (DE 4, 5.) After briefing and oral argument, this Court denied Mylan's motion for a preliminary injunction. (DE 43, 44.)

On November 4, 2011, Apotex and GSK filed Motions for Summary Judgment seeking dismissal of all of Mylan's claims against them. (DE 178, 183.) GSK also filed a Motion to Strike the Expert Report of Mark Gleason, which is Mylan's expert damages report. (DE 187.) Mylan filed a brief in opposition to both summary judgment motions (DE 208), and filed opposition to the Motion to Strike on December 5, 2011. (DE 200.) On December 19, 2011, Apotex and GSK filed reply briefs. (DE 215, 221, 219.)

II. STANDARD OF REVIEW

A court shall grant summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The substantive law identifies which facts are critical or "material." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A material fact raises a "genuine" issue "if the evidence is such that a reasonable jury could return a verdict" for the non-moving party. *Healy v. N.Y. Life Ins. Co.*, 860 F.2d 1209, 1219 n.3 (3d Cir. 1988).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party makes this showing, the burden shifts to the non-moving party to present evidence that a genuine fact issue compels a trial. *Id.* at 324. The non-moving party must then offer admissible evidence

that establishes a genuine issue of material fact, *id.*, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). However, "a party who does not have the trial burden of production may rely on a showing that a party who does have the trial burden cannot produce admissible evidence to carry its burden as to the fact." *Celotex Corp.*, 477 U.S. at 323.

The Court must consider all facts and their logical inferences in the light most favorable to the non-moving party. *Pollack v. American Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986). The Court shall not "weigh the evidence and determine the truth of the matter," but need determine only whether a genuine issue necessitates a trial. *Anderson*, 477 U.S. at 249. If the non-moving party fails to demonstrate proof beyond a "mere scintilla" of evidence that a genuine issue of material fact exists, then the Court must grant summary judgment. *Big Apple BMW v. BMW of N. Am.*, 974 F.2d 1358, 1363 (3d Cir. 1992).

III. DISCUSSION

A. Breach of Contract

Mylan first asserts that GSK is liable for breach of contract. In particular, the parties dispute the construction of the License Agreement and whether it permits the GSK-Apotex Supply and Distribution Agreement. Contract interpretation is "decided by the court as a matter of law unless the meaning is both unclear and dependent on conflicting testimony." *Bosshard v. Hackensack University Medical Center*, 345 N.J. Super. 78, 92 (App. Div. 2001). Under New Jersey law, the "polestar of contract construction is to discover the intention of the parties as revealed by the language used by them." *Karl's Sales & Serv. v. Gimbel Bros.*, 249 N.J. Super. 487, 492 (App. Div. 1991). Where the language of a contract is clear and unambiguous,

however, "it is the function of a court to enforce it as written and not to make a better contract for either of the parties." *Kampf v. Franklin Life Ins. Co.*, 33 N.J. 36 (1960). When a court is tasked with determining the meaning of an agreement, "the terms of the contract must be given their 'plain and ordinary meaning.'" *Kaufman v. Provident Life and Cas. Ins. Co.*, 828 F. Supp. 275, 282 (D.N.J. 1992).

Here, Mylan contends that GSK breached Section II(e) of the License Agreement, as amended, by working with Apotex in order to manufacture and distribute paroxetine hydrochloride extended-release tablets. The parties agree Mylan launched its generic Paxil CR in May of 2008, and there is no dispute that two years elapsed before GSK entered into the Supply and Distribution Agreement with Apotex. (*See* Mylan's Response to GSK's Statement of Undisputed Material Facts ¶¶ 38, 39, DE 207) Section II(e) of the License Agreement provides that at the end of those two years, "GSK or its Affiliate may commence marketing and selling generic paroxetine hydrochloride controlled or modified release products pursuant to its Paxil CR® NDA." Thus, the question before the Court is whether the License Agreement permits GSK to sell authorized generic Paxil CR to Apotex.

Section II(e) identifies two parties that may market and sell generic Paxil CR: GSK or its Affiliate. Importantly, the language does not limit *to whom* GSK or its Affiliate may market and sell generic Paxil CR. In other words, the License Agreement does not limit GSK or its Affiliate to certain purchasers. GSK asserts that it may market or sell generic Paxil CR pursuant to its NDA to whomever it wants. Mylan disagrees, arguing that in order for GSK to market and sell to Apotex, this Court would have to add "or a Third-party of GSK's choosing" to the phrase "GSK or its Affiliate."

Mylan's argument that a third party cannot market and sell generic Paxil CR fails because it assumes that Section II(e) governs what happens after GSK has sold the product. While the License Agreement controls what GSK or its Affiliate may do, it limits neither who purchasers may be nor what those purchasers do with the product. Despite Mylan's insistence that the language requires otherwise, the Court must enforce the contract as written. Accordingly, the Court concludes that the language of the License Agreement is clear and permits GSK to market and sell to whomever it wants, including Apotex.

Next, Mylan asserts that GSK is not "selling" authorized generic Paxil CR as contemplated by Section II(e). To supports its argument, Mylan explains that according to the "common industry understanding," the act of "selling" does not include entering into a supply and distribution agreement with a third-party generic company. (Mylan Br. at 31, 33.) However, Mylan cannot use evidence of industry custom to "modify the terms of a valid, unambiguous license agreement." *Dun & Bradstreet Software Servs. v. Grace Consulting, Inc.*, 307 F.3d 197, 212 (3d Cir. 2002) (citing *Atlantic Northern Airlines v. Schwimmer*, 12 N.J. 293, 302-03 (1953)). The "common industry understanding" Mylan cites is extrinsic evidence, which cannot be used "to create an ambiguity where none exists" in order to preclude summary judgment. *International Union v. Skinner Engine Co.*, 188 F.3d 130, 145 (3d Cir. 1999).

It is undisputed that GSK entered into a supply and distribution agreement with Apotex wherein GSK agreed "to exclusively supply and sell" generic Paxil CR to Apotex for a "supply price" ranging from $10.30 to $13.20 per unit. (Supply and Distribution Agreement at §3.1(a)(i), Schedule 2.2(a)(i); Saveriano Cert. Ex. K.) Consequently, GSK is "selling" generic Paxil CR to Apotex as provided by the basic, plain language in the License Agreement.

Finally, Mylan asserts that Section II(e) requires "marketing *and* selling," but that GSK is not "marketing" generic Paxil CR. GSK counters that the License Agreement does not require it to market generic Paxil CR. (GSK Br. at 16, DE 184.) GSK argues that the License Agreement uses permissive language to define what GSK may do. Indeed, the License Agreement provides that GSK "*may* commence marketing and selling;" it does not state that GSK *shall* or *must* commence marketing and selling. Thus, GSK infers that it does not have to both market and sell generic Paxil CR. In other words, GSK concludes that it may market *or* sell the drug. But Mylan suggests that the word "may" was used in the License Agreement to demonstrate the parties' intention that GSK would have the option, but not be compelled, to market and sell the authorized generic after two years. (Mylan Br. at 32-33.)

However, the Court need not determine whether the License Agreement allows GSK to market *or* sell generic Paxil CR because the undisputed facts demonstrate that GSK did both. During the GSK-Apotex settlement negotiations, Apotex originally wanted an all-cash settlement. Instead, the parties agree that "GSK offered Apotex a combination of cash and a future stream of income," part of which was to be derived from sales of authorized generic Paxil CR. (Mylan's Response to Apotex's Statement of Undisputed Material Facts ¶ 3.) Furthermore, it is undisputed that Apotex never made an unsolicited proposal to GSK to distribute authorized generic Paxil CR. (*Id.* ¶ 7.) Instead, it was GSK advocating for this arrangement; GSK offered to sell authorized generic Paxil CR to Apotex. Therefore, there can be no genuine dispute that GSK marketed authorized generic Paxil CR to Apotex during their settlement negotiations.

In sum, the Court finds the language of the License Agreement is clear and unambiguous. The language plainly states that GSK may commence marketing and selling of authorized generic Paxil CR after Mylan's two-year period of exclusivity. GSK did exactly that. It

marketed and sold authorized generic Paxil CR to Apotex. Therefore, GSK is entitled to summary judgment dismissing Mylan's breach of contract claim.

B. Breach of the Covenant of Good Faith and Fair Dealing

Mylan next accuses GSK of breaching the implied covenant of good faith and fair dealing when it entered into the supply and distribution agreement with Apotex. In particular, Mylan argues that GSK frustrated the parties' intentions when GSK entered into the Supply and Distribution Agreement with Apotex.

New Jersey law imposes upon the parties to a contract a duty of good faith and fair dealing. *Brunswick Hills Racquet Club, Inc. v. Route 18 Shopping Ctr. Assocs.*, 182 N.J. 210, 224 (2005). "The covenant of good faith and fair dealing calls for parties to a contract to refrain from doing 'anything which will have the effect of destroying or injuring the right of the other party to receive' the benefits of the contract." *Id.* at 224-25 (quoting *Palisades Props., Inc. v. Brunetti*, 44 N.J. 117, 130 (1965)). Proof of "bad motive or intention" is required because contract law does not require parties to act altruistically towards each other, and "decisions that happen to result in economic disadvantage to the other party are of no legal significance." *Wilson v. Amerada Hess Corp.*, 168 N.J. 236, 251 (2001) (citations omitted).

To support its claim, Mylan points to its intention during settlement negotiations "that GSK not be permitted to authorize a third-party generic company to market and sell" authorized generic Paxil CR. (Mylan's Br. at 48.) Mylan asserts that this objective was reflected in the original License Agreement. (*Id.*) However, GSK and Mylan amended the License Agreement to permit GSK to market and sell the authorized generic product after two years, and Mylan

cannot use the covenant of good faith and fair dealing to supersede this express term in the License Agreement. *See Sons of Thunder v. Borden, Inc.*, 148 N.J. 396, 419 (1997).

But Mylan contends that "any amendment in response to the FTC's concerns" was supposed to "preserve the parties' originally negotiated economic positions." (Mylan Br. at 48.) The Second Amendment to the License Agreement, Mylan concludes, failed to do this. (*Id.*) But there is no contention that Mylan objected to or did not freely enter into the amended License Agreement. The final License Agreement plainly allows GSK to "commence marketing and selling generic paroxetine hydrochloride controlled or modified release products pursuant to its Paxil CR® NDA." Therefore, GSK's choice to market and sell authorized generic Paxil CR to Apotex, even if it "resulted in economic disadvantage" to Mylan, is legally insufficient to demonstrate a breach of the covenant. *Wilson*, 168 N.J. at 251.

More importantly, Mylan failed to carry its burden of demonstrating bad motive or intention on the part of GSK when it entered into the Supply and Distribution Agreement with Apotex. While the final License Agreement may not reflect Mylan's original economic objectives, Mylan has offered no evidence of bad motive or intention. Accordingly, Mylan's claim of breach of the covenant of good faith and fair dealing fails as a matter of law, and GSK is entitled to summary judgment.

C. Inducement to Breach Contract

Mylan alleges that Apotex, by executing the Supply and Distribution Agreement with GSK, induced GSK to breach the License Agreement. "[O]ne who willfully induces or improperly causes a party to a contract to break its contract with another party is liable to that other party for damages caused by the breach." *Norwood Easthill Assocs. v. Norwood Easthill*

Watch, 222 N.J. Super. 378, 383 (App. Div. 1988) (citing *Louis Schlesinger Co. v. Rice*, 4 N.J. 169 (1950)). In this case, however, the Court has determined that GSK did not breach the License Agreement. Therefore, Mylan's claim that Apotex induced breach of contract necessarily fails as a matter of law. The Court will enter summary judgment in favor of Apotex on this claim.

D. Tortious Interference with a Contract

Mylan alleges that Apotex tortiously interfered with the License Agreement. To succeed on this tort under New Jersey law, Mylan must prove (1) a protectable right (i.e., a contractual relationship); (2) interference with that protectable right, done intentionally and with malice; (3) the interference caused the loss; and (4) the interference caused damage. *Printing Mart-Morristown v. Sharp Elec. Corp.*, 116 N.J. 739, 751 (1989). For purposes of this tort, "malicious" means "that the harm was inflicted intentionally and without justification or excuse." *Id.* (quoting *Rainier's Dairies v. Raritan Valley Farms, Inc.*, 19 N.J. 552, 563 (1955)).

Here, Mylan asserts its protectable right is its contractual ability to prevent GSK from marketing and selling authorized generic Paxil CR to third-party generic companies. But the Court has determined that Mylan currently has no such right. The License Agreement provides that Mylan's market exclusivity lasts two years from the time it begins selling paroxetine. After those two years, GSK may commence marketing and selling authorized generic Paxil CR to whomever it chooses. Regardless of whether Apotex knew of the exclusivity period, Apotex could not have interfered with it. It is undisputed that Mylan's exclusivity period ended in May 2010, two years after it began selling generic Paxil CR. Apotex entered into the Supply and Distribution Agreement with GSK in July 2010. Therefore, as a matter of law, Apotex could not

have interfered with a protectable right that was extinguished two months prior. As Mylan cannot demonstrate the first element of its tortious interference claim, summary judgment against it is appropriate.

E. Motion to Strike the Expert Report of Mark Gleason

At this juncture, the Court notes that it is unnecessary to determine whether and to what extent Plaintiffs suffered damages as a result of the alleged conduct. The Court has determined that GSK and Apotex are entitled to summary judgment dismissing each claim against them. The Expert Report of Mark Gleason is Mylan's expert damages report and is therefore not required for the disposition of this case. As a result, GSK's Motion to Strike the Expert Report of Mark Gleason will be denied as moot.

IV. CONCLUSION

For the foregoing reasons, the Court grants GSK's Motion for Summary Judgment. The Court further grants Apotex's Motion for Summary Judgment and denies GSK's Motion to Strike the Expert Report of Mark Gleason as moot. An appropriate order is filed herewith.

Dated: February 23rd, 2012

United States District Judge